k041112

SECTION 2: 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92.

I. General Information

Establishment	Siemens Medical Solutions, Inc. 51 Valley Stream Parkway Malvern. PA 19355
Registration Number	2240869
Manufacturer	Siemens AG. Bereich Med Henkestrasse 127 D-91052 Erlangen. Germany
Registration Number	8010024
Contact Person	Ms. Nealie Hartman Technical Specialist. Regulatory Submissions 51 Valley Stream Parkway E50 Malvern. PA 19355 Phone: (610) 448-1769 Fax: (610) 448-1787
Device Name	Trade Name: MAGNETOM Espree System Classification Name: Magnetic Resonance Diagnostic Device CFR Code: 21 CFR § 892.1000 Classification: Class II

Performance Standards
None established under Section 514 the Food, Drug and Cosmetic Act.

II. Safety and Effectiveness Information Supporting Substantial Equivalence.

Intended Use
The MAGNETOM Espree is indicated for use as magnetic resonance diagnostic device (MRDD) that produces transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head, body, or extremities. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM Espree may also be used for imaging during interventional procedures when performed with MR compatible devices such as, in room display and MR safe biopsy needles.

Device Description
The MAGNETOM Espree System is a 1.5 T closed superconducting magnet designed scanner. It consists of the same types of hardware (with a modified gradient coil. RF body resonator and magnet) that is currently available with MAGNETOM Avanto.

Substantial Equivalence
The system is substantially equivalent to the following cleared medical devices:

Predicate Device Name	*FDA Clearance Number*	*FDA Clearance Date*
Siemens MAGNETOM Avanto	K032428	October 16, 2003

General Safety and Effectiveness Concerns:
Operation of the MAGNETOM Espree System is substantially equivalent to the commercially available MAGNETOM Avanto. Specified by the FDA guidance document for MR Diagnostic Devices that will be evaluated, below are the safety parameter with the following levels:

Action Levels
- Maximum Static Field
- Rate of Change of Magnetic Field
- RF Power Deposition
- Acoustic Noise Levels

Performance Levels
- Signal to Noise
- Image Uniformity
- Geometric Distortion
- Slice Profile. Thickness and Gap
- High Contrast Spatial Resolution

The MAGNETOM Espree will conform to the FDA recognized NEMA Standards for the measurement of performance and safety parameters and the international IEC standard for safety issues with Magnetic Resonance Imaging Devices. This will assure that the performance of this device can be considered safe and effective with respect to the currently available MAGNETOM Avanto.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2004

Ms. Nealie Hartman
Technical Specialist
Siemens Medical Solutions, Inc. USA
51 Valley Stream Parkway
MALVERN PA 19355

Re: K041112
Trade/Device Name: MAGNETOM Espree
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 LNH and LNI
Dated: April 26, 2004
Received: April 28, 2004

Dear Ms. Hartman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known) K04 1112

Device Name: **MAGNETOM Espree**

Indications for Use:

The MAGNETOM Espree is indicated for use as magnetic resonance diagnostic devices (MRDD) that produce transverse, sagittal, coronal and oblique cross sectional images, spectroscopic images and/or spectra, and that display the internal structure and/or function of the head, body, or extremities. These images and/or spectra when interpreted by a trained physician yield information that may assist in diagnosis.

The MAGNETOM Espree may also be used for imaging during interventional procedures when performed with MR compatible devices such as, in room display and MR safe biopsy needles.

(please do not write below this line- continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter Use ____

David A. Lynn

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K04 1112